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16. ABSTRACT

A new limited access facility located in the Environmental Research Center was conceived as a result of the need for laboratories for testing hazardous materials found in the environment. The Genetic Toxicology Division (GTD) research personnel had the expertise and proven test procedures for this type of work, however the proper facility was not available. To accomplish the design of the facility, the GTD used its own experience and expertise for design ideas. Design considerations include room air flow and filtration, hood types, sink design and placement, design of countertops, type of flooring and wall sealent, and traffic flow within the laboratories. These laboratories required the diversity to handle weighing of stock hazardous materials, preparation and handling of aliquots, maintenance of dosed animals as well as sterile conditions required for tissue culture and continuous cell culture methods. All these operations had to be performed in a safe work environment for laboratory personnel. The new genotoxic facility poses unique safety and health program requirements. The requirements include specific dress (e.g., scrub suit, Tyvek jumpsuit, gloves, safety glasses and safety shoes), safety advisory group, safety response group, medical monitoring program and training of current and new staff members.

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Design of a Limited-Access Facility and Safety Program for a Genetic Toxicology Laboratory[A]

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A limited-access facility has been designed as a result of the need for laboratories for testing hazardous materials found in the environment. The facility design features include room air flow and filtration, hood types, sink design and placement, design of countertops, type of flooring and wall sealant, and traffic flow within the laboratories. These laboratories required the diversity to handle weighing of stock hazardous materials, preparation and handling of aliquots, maintenence of dosed animals as well as sterile conditions required for tissue culture and continuous cell culture methods. A safety and health program was also developed which included specific dress (*e.g.*, scrub suit, TYVEK® jumpsuit, gloves, safety glasses and safety shoes), safety advisory group, safety response group, medical monitoring program and training of current and new staff members. The design and use of the facility are continuously reevaluated and changes are made as necessitated by either research needs or improved safety methods.

Introduction

An important area of research that often requires specialized facilities encompasses the field of mutagenesis, carcinogenesis, and cellular toxicology. Evaluation of the mutagenic and carcinogenic potential of environmental chemicals and complex environmental mixtures is an important part of this research. The process of evaluation of potential environmental genotoxicants is approached through the stepwise application of bioassay methodologies involving short-term bioassays and, eventually, established whole-animal mutagenesis and carcinogenisis bioassays. Because this is a research facility, and not an industrial facility (*i.e.*, with manufacturing capabilities), the amount of hazardous materials used are extremely small — generally in the milligram range of any particular agent. However, due to the hazardous nature of some of the chemicals, this facility required the

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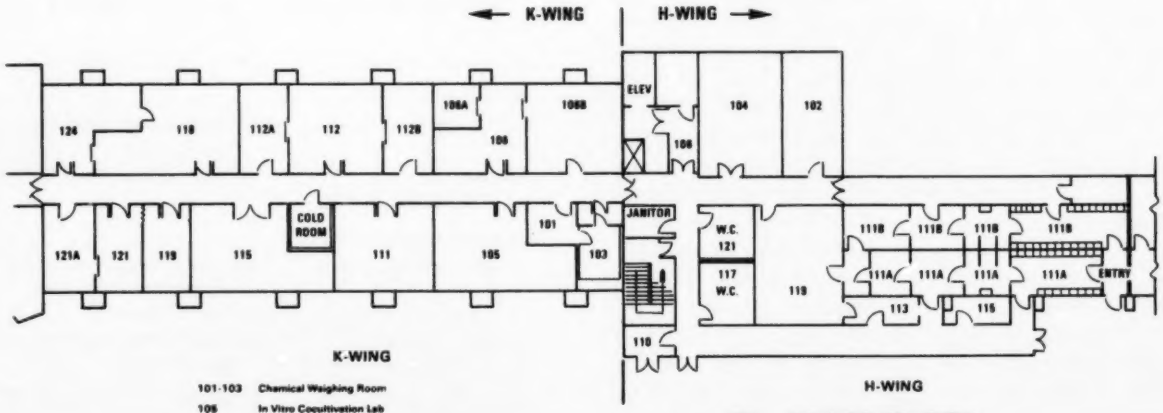

Figure 1 — The floor plan of the limited-access facility.

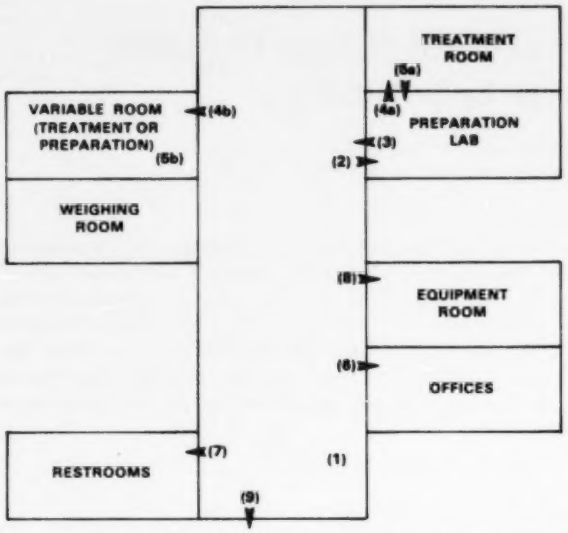

Figure 2 — Schematic of the work areas and related movement. See Table I for appropriate dress requirements.

diversity to handle weighing of stock hazardous materials, preparation and handling of aliquots, maintenance of dosed animals, as well as sterile conditions required for tissue culture and continuous cell line growth. All these operations need to be performed in a safe work environment for laboratory personnel.

Design of a Limited-Access Facility

Facility

The facility located in the Environmental Research Center, Research Triangle Park, N.C. was conceived as a result of the need for laboratories which would provide improved safety for genetic toxicology research on hazardous chemicals found in the environment. The facility was designed by a committee from the Environmental Research Center Safety Office, Building Facilities Branch, and the research personnel as well as the experience of others.[1] In addition, mechanisms have been developed for input and recommendations from the users of the facility, and consequently, the procedures for daily operations within the facility are continuously being reevaluated and revised when necessary. The major problem we faced was designing a facility of this caliber within an existing three story building. An architectural and engineering firm was engaged to provide the design and engineering plan. The floor plan in Figure 1 shows the general layout of the facility, which consists of thirteen laboratories, a sterility/dishwashing room, a weighing room, a common-use instrument room, an animal room, and a change/shower area.

The completed facility prevents all entry of nonauthorized personnel from the exterior by use of computerized card readers and alarmed doors and is therefore referred to as a limited-access facility. Because it is necessary for personnel in other parts of the building to exit through the facility in case of an emergency, some of the doors have audible alarms to prevent entry instead of using locks. The only other entry into the facility is the elevator. The elevator has a card operated control instead of a button and is only used for the delivery of supplies and other personnel authorized to enter the facility receiving area.

The main entry into the facility is through a foyer with doors leading into the two locker rooms. The locker room doors open into the hallway leading to the work area. A second entry is located at the opposite end of the facility (Figure 1). Within the work area there are varying degrees of potential exposure, a schematic of these areas and the related movement is shown in Figure 2. The required dress for each of these areas with varying degree of potential exposure is shown in Table I. The offices, corridor and restrooms are to be "free" of potential contamination. The dress and other procedures (*i.e.* transfer of carcinogens) are performed so as to maintain the cleanliness of the areas.

In the final design of the limited-access facility, some of the laboratories were designed so that all "treatments" could be confined to particular rooms. In other laboratories, all operations are performed within the same room. These are refered to as a variable room (Figure 2 and Table I). Research personnel working in this latter situation do not at all times have to wear the full protective clothing defined in

TABLE I
Dress Requirements For a Limited-Access Facility and Related Movement

Movement[A]	Dress Requirements
1. Enter the Corridor	Safety shoes or shoe covers over street shoes
2. Enter Prep Laboratory (Eye Protection Required)	Add TYVEK jumpsuit over street clothes or TYVEK labcoat over scrub suit
3. Leaving Prep Laboratory	Street clothes or scrub suit
4. Enter Treatment Room	
a. From Prep Laboratory	Remove labcoat, add full covering (see Table II)
b. From Corridor (Variable Room)[B]	Add full covering (see Table II)
5. Leave Treatment Room	
a. Into Prep Laboratory	Remove jumpsuit and dispose of in treatment room; add TYVEK labcoat
b. Into Corridor (Variable Room)	Remove jumpsuit and dispose of in treatment room
6. Enter Technician Desk Space	Street clothes or scrub suit (no lab coats allowed)
7. Entering Restroom	Street clothes or scrub suit
8. Entering Equipment Room (Eye Protection Required)	Add TYVEK labcoat over scrub suit or TYVEK jumpsuit over street clothes
9. Leaving Barrier	Change out of scrub suit and safety shoes

[A]Numbered items refer to movements shown in Figure 2.
[B]Room that is used as both a preparation and treatment laboratory.

Table II. People entering such rooms are required to dress for the highest potential exposure in progress in the room at that time. A sign indicating appropriate dress is posted.

TABLE II
Required Dress When Handling Materials Requiring Safety Protocols

1. Scrub suit (launderable jumpsuit or top and pants) are required.
2. TYVEK jumpsuit (including gauntlets to cover wrist if jumpsuit does not fit because of size problems).
3. Gloves — 2 pairs.
4. Shoe covers.
5. Safety glasses.
6. Safety shoes.

Optional: headcovering, respirator, surgical dust face mask.

In mixed function rooms, for all individuals entering the room, (where both treatment and preparation activities are performed) the dress will be appropriate for the most hazardous activity being conducted. The door must have a sign to indicate when hazardous agents are in use and the dress required.

Flooring

The floor in the work area is concrete covered with an impervious PVC flooring with heat fused seams and cushioned backing. This flooring is the most chemical resistant material available and when installed was sealed with epoxy adhesive. To prevent splattering on the walls in case of a spill the floor was extended up the walls 8 centimeters. The walls above the flooring are painted with an epoxy paint. The ceiling is a plastered ceiling with sealed access panels, which allow access to all of the services located above the ceiling.

Air Handling System

The air handling system is controlled by a monitoring panel located in the hallway. The panels permit personnel to monitor the air flow in each room before entry. The single-pass air handling system is a special design to allow the supply air to track the exhaust. The supply air is HEPA filtered and temperature and humidity controlled. All exhaust air is removed via stainless steel ducts through HEPA and activated charcoal filters to the outside of the building. All components of the exhaust systems are upstream of the blowers. This arrangement allows the entire exhaust system to maintain a negative pressure when operating. The panels furnished by Air Monitoring Company (San Rosa, CA) control the exhaust air and supply air in one operation. If the amount of exhaust air deviates from its setting, the supply air will automatically compensate for the change to maintain the negative status of the lab. Any change of 10% or more will cause the alarm system to activate allowing the personnel to evacuate the affected laboratory until the problem can be corrected.

Hoods

Hoods in the laboratories are of three different types. Class I Chemical Fume Hoods allow use of chemicals where no sterility is necessary, but protection of the worker is essential. The air used by these hoods is supplemented with outside non-sterile air to reduce loss of filtered and conditioned room air. The second tvpe of hood is a Class II, Type B, Biological Safety Cabinet with 30% recirculation of internal air. These hoods are used when a sterile work area is essential, and protection of the technician is important. This type of hood is limited to use of nonvolatile materials because of the internal air recirculation. The third type of hood is the Class II, Type B, Biological Safety Cabinet with total exhaust. This hood provides a sterile work area, researcher protection and no internal air recirculation. This type of hood is ideal for bioassay treatments with potentially volatile chemicals but is limited in use due to amount of treated room air required for it to function. All hoods utilized in the limited access facility meet established specifications.[2]

Gas Cylinder/Deionized Water/Other Features

The gases and deionized water are piped into the facility to prevent cylinders from being located in the laboratories. The cylinder pressures can be monitored from inside the facility. When it is necessary to change these cylinders, this can be accomplished without maintenance personnel entering the restricted area. Other special safety features in the laboratories are foot valves to control the water at the sinks, sliding doors to prevent pressure changes when entering the treatment rooms, top cabinets extending to the ceiling, stainless steel cabinet tops, eye washes, exhausted incubators, and an intercommunication system to provide a hand-free communication link between the preparatory and treatment laboratories. Treatment rooms with the potential for higher hazard are equipped with view windows, which allow visual monitoring of the personnel working at the hoods in the treatment rooms.

Weighing Room

The weighing room is a separate room designed for handling stock quantities of test materials. This room is a 3-meter by 3-meter metal room located inside an outer room. The inner room, which has a negative air flow, contains a stainless steel glove box, a freezer, a refrigerator and has entry and exit doors. The weighing room is equipped with all of the same safety equipment as the laboratories. Entry into the weighing area is through an anteroom where the laboratory personnel put on protective clothing when using the facility. Exit from the weighing room is through a small change area equipped with a sink for hand washing.

Animal Room

The animal room is a special room for working with treated animals. It has all of the features designed into the other laboratories plus additional features described below. The hoods located in the animal room are hoods with "pass-thoughs" to pass animals or materials from one hood to another without bringing them outside the contained area. The animal cage housing is exhausted to the outside with a continuous flow of air inward over the cages at 30 cubic meters. These cage housings permit working with or removal of the animals with ease and at the same time protect the laboratory personnel from contamination. When leaving the

facility, personnel inside the animal facility will leave directly through the shower area.

Safety Program For a Genetic Toxicology Laboratory

Safety Management Stucture

The safety management structure for the limited-access facility consists of a facility safety officer, safety advisory group and a safety response group. This safety program is coordinated through the safety office for the entire Environmental Research Center (Center Safety Office) and all protocols and procedures for handling hazardous chemicals are reviewed for approval by the Center Safety and Health Committee.

The facility safety officer (FSO) coordinates all activites with the Center Safety Office with the assistance of the senior research staff. Other duties of the FSO are as follows: 1) to plan, develop, and coordinate a program to promote safe working procedures and conditions; 2) to perform periodic safety surveys; 3) to identify safety deficiencies, implement abatement action, and coordinate safety training; 4) to provide occupational safety and health information and obtain professional assistance as required; 5) to advise and assist principal research investigators in the preparation of accident reports, to review the accident data, and to suggest corrective action; 6) to implement local programs to assure that personal protective equipment is available where needed; and 7) to serve on the Center Safety and Health Committee.

The FSO is advised by the safety advisory group and facility safety response group. The safety advisory group and safety response group are composed of individuals who actually work in the facility and principal research investigators.

The safety advisory group addresses day-to-day operational safety concerns and serves as a conduit for concerns of the technical staff. The group also: 1) trains new employees and existing employees on the safety procedures for new equipment or new procedures; 2) recommends new procedures when necessary to coordinate with other existing safety procedures; and 3) is responsible for the updating and revision of the facility safety protocols.

The main responsibility of the facility safety response group (FSRG) is to stabilize spills and/or accidents in the facility when the spill and/or accident exceeds the capability of the individual(s) involved in the spill and/or accident. Each member of the FSRG is required to complete an eight-hour safety orientation session and several mini-safety workshops held throughout the year. During the initial orientation session, each member is issued a copy of the FSRG Safety Protocol; Pageboy pager, and a chemical spill clothing kit that consists of safety glasses, nitrile gloves, half-face respirator with charcoal and HEPA filters; and a polylaminated TYVEK® total body coverall.

Each member is also given ample opportunity to familiarize themselves with the FSRG emergency spill cart, which consists of the following equipment: 1) chemical spill clothing kits; 2) biohazard, chemical and radioactive spill pillow kits; 3) emergency face and body wash solutions; 4) disposable emergency blankets; 5) standard first aid kits; and 6) facility safety response group protocol.

Chemical Spills

In the event of a hazardous chemical/carcinogenic *contained spill* (a spill within a completely enclosed container or one restricted to an area covered with disposable plastic-backed paper), the person responsible for the spill will clean up the area.

If a *non-contained spill* occurs, the individual responsible for the spill must notify: 1) the FSO/FSRG; 2) the medical emergency operation team (EOT), if a medical emergency; 3) the supervisor and/or principal investigator; and 4) the Center Safety Office. The FSRG will determine if an emergency situation exists. In the absence of the supervisor (principal investigator), the FSRG will assume interim authority and will decide the course of action. In the event of a spill with personal injury but no personal contamination, the FSRG will assist the EOT in entering the facility and assist in transporting the injured employee as well as in the cleanup of the spill. If the spill involves both personal injury and personal contamination, the FSRG will assist the EOT in entering the facility, assist in the personal decontamination, and in transporting the individual for medical treatment. The FSRG will also assist in the decontamination of the spill site. A written report to the Center Safety Office must be prepared which describes the accident, how the cleanup/decontamination was accomplished, and how future accidents of this nature can be prevented.

During the course of cleanup/decontamination of a contained and uncontained spill area, the FSRG will wear the following protective ensemble: 1) polylaminated TYVEK® total body coverall, 2) nitrile and viton gloves, 3) Durafab Saranex laminated TYVEK® coverall with respirator hood, and 4) a Bullard motor driven air pump that will be used to supply breathable air to the TYVEK® Saranex coverall via an umbilical cord.

To ensure that the Bullard motor driven air pump is not supplying air contaminated by the spill, the FSRG will determine the best location for the pump's air intake canister which can be located as far as 95 meters from the actual pump. In addition, a member of the FSRG will be assigned to remain at the air intake source throughout the cleanup/decontamination period.

The FSRG will provide the same protective ensemble to the individual(s) who committed the spill, along with the appropriate cleanup/decontamination spill kit and protocol. To facilitate prompt cleanup of all contained and uncontained spills within the facility, the completely stocked emergency spill cart (mentioned in the section safety management structure) is utilized.

Upon the completion of the cleanup/decontamination of the spill area, a swab test will be performed by the FSRG to determine if any residue is still present at the spill site. After completing the swab test, the swab tip will be assayed using the Ames test and/or mass spectrometric analysis.

Training

Personnel training commences with a New Employee Safety Checklist that must be signed by the appropriate senior staff, facility safety officer, and the Center Safety

Office prior to handling potentially hazardous chemicals. At this time all pertinent rules, regulations, and safety equipment are reviewed. Additionally, all new staff members will be given a guided tour of the facility, and issued a complete copy of the Center's Safety Manual and appropriate project and facility protocols. On-the-job training is provided through demonstrations, practice sessions with experienced staff, and seminars on safe handling of toxic chemicals, use of hoods, wieghing room, and other related topics.

Hazardous Chemicals/Carcinogens

Requests to use hazardous chemicals/carcinogens within the facility are submitted to the Center Safety Office by the principal investigator. The investigator submits a completed protocol form. After approval, the hazardous chemicals/carcinogens are logged in by the weighing room staff who maintain records on the amounts and chemical/physical properties of each chemical in the facility. Disposal of all hazardous waste is accomplished by one of two methods: 1) incineration or 2) burial in an approved landfill.

Medical Monitoring Program

A medical program to monitor, insofar as possible, the health risks in the laboratory is furnished to each employee through the Center Safety Office. There are several guidelines available for such a program.[3-6] Medical examinations are scheduled annually or more frequently based on the physician's recommendations. Prior to the annual medical examination, each employee completes an occupational history that is forwarded to the safety office and the consulting physician. In addition, all new laboratory employees are supplied a pair of safety glasses and safety shoes.

Concluding Remarks

A laboratory facility used for performing genetic toxicology must be designed to permit the safe use of hazardous materials (*e.g.* mutagens, carcinogens, and teratogens) as well as to provide sterile conditions for cell culture. Design considerations include room air flow and filtration, hood types, sink design and placement, design of countertops, type of flooring and wall sealant, and traffic flow within the labs. Safety management is integrated into the operations of the facility.

Personnel who work within the facility participate in specialized training prior to initiating work. This training includes: 1) general safety with emphasis on the proper handling of hazardous materials; 2) certification of proper use of glove boxes; and 3) detailed procedures to follow during emergencies.

The development and use of such a facility is an ongoing process, and modifications in the structure and procedures may be made. A continuing evaluation of the facility permits necessary changes and improvements to be made as changing needs and research requirements necessitate.

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